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REPORTING GUIDE FOR INITIAL REPORTS AND MODEL CHANGE REPORTS ON SUNLAMPS AND SUNLAMP PRODUCTS (21 CFR 1002)

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

Center for Devices and Radiological Health
Rockville, Maryland 20857

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INTRODUCTION

Sunlamp products and ultraviolet lamps manufactured after May 6, 1980 that are used for skin tanning must comply with the Federal Performance Standard for sunlamp products set forth in 21 CFR 1040.20, and must be certified by the manufacturer as set forth in 21 CFR 1010.2.

This reporting guide has been prepared to assist manufacturers in the preparation of initial and model change reports concerning sunlamps and ultraviolet lamps which are subject to the Federal Performance Standard.

The reporting and recordkeeping requirements are specified in Part 1002 of the regulations published under the authority of the Radition Control for Health and Safety Act of 1968 (Title 21, Code of Federal Regulations, Chapter I, Subchapter J). Part 1002.10 of the Regulations requires the submission of an initial report for products listed in Part 1002.61. A complete report is required for each product model or model family. A model family is a group of two or more product models having basically similar design, performance features and intended function, and which are manufactured using the same or very similar quality control and testing procedures. The information reported for any model within a model family must be largely the same as the information reported for every other model within the same family.

The Bureau suggests that a complete report on one model of a model family be submitted with a supplemental report for each of the other models in the family. These separate supplemental reports should respond to the appropriate parts of the guide and report the differences in detail, referencing the number of the affected item. However, the supplement must clearly indicate those items of the supplemental report that are the same as the original report.

When there are changes in the model or model family that alter the emission or radiation safety characteristics of the reported product, a supplemental report must be submitted to the Bureau. Supplemental reports are also required for new models belonging to a previously reported model family. These types of reports should also respond to the appropriate parts of the guide. Where there is no change from a prior report this fact must be so stated. Report the changes in detail and reference the number of the affected item. However, the supplemental report must clearly indicate those items of the part which have not been changed. A new model family must be reported as a model change report. This type of report must also respond to all the appropriate parts of the guide. However, cross referencing of other reports should be minimized in order to reduce reporting errors and to avoid confusion.

Manufacturers who do not manufacture the ultraviolet lamps for their products need not respond to Part 3 of the guideline. Those who manufacture only the ultraviolet lamps need not respond to Part 2.

Your reports should conform to the organization and item enumeration of this guide (as specified in 21 CFR 1002.7) to ensure the inclusion of the information requested, to facilitate review, and to minimize follow-up correspondence.

Many of the responses solicited by this guide can be made in the space provided. Where attachments are required, so indicate in the space provided in the body of the guide. Attachments should be numbered the same as the specific item of this guide to which they are addressed. For example, an attachment responding to Item 2.2.1 should be labeled Attachment 2.2.1. If a question is not applicable to your product, write N.A. next to that question. Every question must have a response.

There are special problems associated with the group of sunlamp products called "tanning booths" or other similar equipment for whole body exposure for tanning purposes. Therefore, in addition to meeting the requirements of the Sunlamp Product Performance standard (Part 1040.20 of Title 21, Code of Federal Regulations) these products are to be manufactured and used in accordance with the recommendations given in Appendix A of this guide.

Your reports and report supplements are to be submitted to:

Director (HFZ-300)
Office of Compliance
Center for Devices and Radiological Health
8757 Georgia Avenue
Silver Spring Maryland 20910

When reports are received, an accession number will be assigned to each report and a letter acknowledging receipt will be issued. If you have any questions, please contact the Consumer-Industrial Products Branch of the Division of Compliance (301) 427-7228

P A R T 1

MANUFACTURER, PRODUCT AND REPORT IDENTIFICATION

1.1 Manufacturer of Reported Product:

Name of Company _____

Address _____

1.2 Importer: (complete if applicable)

Name _____

Address _____

1.3 Name and Title of person preparing this report

Signature _____

Name and Title _____

Telephone Number _____

1.4 Identification of Report.

1.4.1 Is this report filed pursuant to Part 1002.61(a) of Title 21, Code of Federal Regulations?
YES___NO___

1.4.2 Date of Report_____.

1.4.3 Is this an initial report___, model change report___, or a supplemental report___?

1.4.4 If it is a supplemental report, give BRH accession number and date of initial or model change report_____.
(Accession No.) (Date)

1.5 Identification of Product.

1.5.1 Provide the model designation (name and model number). If model is a member of a model series or family, also provide a series or family designation.

_____

_____

1.5.2 Specify the type of product being reported. Lamp_____

Fixture_____ Fixture with lamp_____ Other_____
(Specify)

1.5.3 Do you supply the reported product to other manufacturers or suppliers for sale under a different name or as a component of another product? YES___ NO___

If the answer is yes, give the following information:

Model Number	Brand	Name & address of company under whose name product is sold

P A R T 2

SUNLAMP PRODUCTS

(THIS PART IS TO BE COMPLETED WHEN THE REPORTED PRODUCT IS A SUNLAMP PRODUCT AS DEFINED IN 21 CFR 1040.20(b)(9)).

2.1 Attach a detailed description of the sunlamp product. If the product is to be installed as a semi-permanent or permanent fixture describe in detail the installation. Also, give a detailed description of the exterior and interior structures of the assembled product and their functions, e.g., cabinet, reflectors, filters, lenses, etc. Include in the description photographs and diagrams which include parts identification. If the reported product is intended to be mounted on a stand or the wall or on some other holding device, describe the configuration in which it is to be mounted and the mechanism anticipated for mounting it. If the product is a suntanning booth describe the physical aids to keep user in the proper exposure position, protective lamp barriers, means of booth entry and exit, and means of user support (refer to Appendix A).

INFORMATION ATTACHED _____ (See Introduction for explanation of method to be used for identification to cross reference all attachments).

2.2 Electrical Circuitry and Operating Conditions

2.2.1 Provide an electrical circuit diagram of the reported product.

If the product is a suntanning booth, include a detailed description of how potential electrical hazards to users and service personnel have been minimized if not eliminated.

INFORMATION ATTACHED? YES___NO___

2.2.2 How many ultraviolet lamps are there in the product?_____

Give the name of the manufacturer, model number and electrical ratings for each lamp._____

2.2.3 Does the sunlamp product incorporate a control on the product to enable the user manually to terminate radiation emission at any time without disconnecting the electrical plug or removing the ultraviolet lamp (21 CFR 1040.20(c)(3))? YES____NO____

If the answer is no, explain in detail the other means for providing the radiation safety or protection intended by this requirement.* _____

*An approved variance (21 CFR 1010.4) is required before an alternate means may be used to provide for the radiation safety or protection intended by 21 CFR 1040.20(c).

2.2.4 Timer

2.2.4.1 Does the product have a timer to control duration of radiation emission from the product (21 CFR 104020(c)(2))? YES____NO____

If the answer is no, explain in detail the other means for providing the radiation safety or protection intended by this requirement.*_____

2.2.4.2 In what units of time is the timer marked? _____ What is the maximum time interval in minutes for which it can be set?_____ What is the minimum time interval in minutes for which it can be set? _____

2.2.4.3 Can the timer be reset before the end of the preset time interval? YES____NO_____

2.2.4.4 Is the maximum error of any timer interval greater than ± 10 percent of the maximum timer interval? YES____NO_____

2.2.4.5 What is the maximum timer interval error expressed as a percent of that interval? ± _____ percent Specify the timer interval. _____

2.2.4.6 When radiation emission from a sunlamp product has been terminated for any reason, including termination by a timer, is resumption of such emission possible without manual activation by user? YES____NO____

If no, is resumption of such emission possible by manual activation by a person other than user? YES____NO____

2.3 Base or Socket Information

2.3.1 What kind of a base is used for each lamp in the product (mogul screw base, medium bipin, etc.), as designated by an American National Standard? _____

_____

*An approved variance (21 CFR 1010.4) is required before an alternate means may be used to provide for the radiation safety or protection intended by 21 CFR 1040.20(c).

2.3.2 If the lamp bases or sockets used do not conform to a particular American National Standard, attach their descriptions, photographs or drawings.

DESCRIPTION ATTACHED? YES___NO___

2.4 Eye Protection

2.4.1 Do you supply protective eyewear that is opaque in the 180-320 nm wavelength region with your product? YES____NO_____
If you do, give the number of sets supplied _____, and, the manufacturer's name_____, address_____, and model designation_____, of the protective eyewear; also, provide a description of the eyewear including measurements of its spectral transmittance (in percent of incident radiation) in the wavelength regions:

180-320 nm (%)

320-360 nm (%)

360-400 nm (%)

400-710 nm (%)

DESCRIPTION ATTACHED? YES___NO___

2.4.2 Can the user see clearly enough while wearing the protective eyewear to reset the timer and read the labels? YES___NO___

2.5 Compliance With Labeling Requirements

2.5.1 Submit a sample of the required certification label (21 CFR 1010.2) or a facsimile if the label is not available at the time of reporting or is inscribed on the reported product.
SAMPLE ATTACHED? YES____ NO____

2.5.1.1 Is the certification label permanently affixed or inscribed on the reported product? YES_____NO____

If no, explain _____

_____

2.5.1.2 Is the certification label legible and clearly visible when the reported product is fully assembled and ready for use? YES____ NO____ If no, explain _____

_____

2.5.2 Submit a sample of the required identification label (21 CFR 1010.3) or a facsimile if the label is not available at the time of reporting, or is inscribed on the reported product or product container. SAMPLE ATTACHED? YES____ NO____

2.5.2.1 Is the manufacturer's name, complete address, month, year, and place of manufacture provided clearly and legibly without abbreviation, and with the year shown as a four-digit number as in the following example? Manufactured: August 1976. YES___NO__

2.5.2.2 Is the identification label permanently affixed or inscribed on the reported product? YES____NO

—

2.5.2.3 Is the identification label legible and clearly visible when the reported product is fully assembled and ready to use? YES____NO____

If no, explain

_____

2.5.3 Submit a sample of the warning label (21 CFR 1040.20(d)(1)) required to be affixed to the product (or facsimile if the label is not available at the time of reporting, or is inscribed on the reported product). SAMPLE ATTACHED? YES___NO__

2.5.3.1 Is the warning label properly worded as required by 21 CFR 1040.20(d), does it recommend a minimum use distance specified both in meters and feet (inches), and does it recommend a maximum exposure time in minutes? YES____NO____

Does the label recommend the duration frequency and spacing of sequential exposures? YES____NO____

2.5.3.2 Is the warning label permanently affixed or inscribed on the reported product? YES____ NO____

2.5.3.3 Is the warning label legible and clearly visible when the reported product is fully assembled and ready to use? YES____ NO____ If no, explain_____

_____

2.5.4 Do the ultraviolet lamps sold with your sunlamp product have labels as reuqired by 21 CFR 1040.20(d)(2)? YES___NO____

2.5.4.1 Do the warning labels contain the words "SUNLAMP-DANGER-ULTRAVIOLET RADIATION. Follow instructions"? YES____NO____

2.5.4.2 Do the warning labels contain the words "Use ONLY in fixture equipped with a timer"? YES___NO___

2.5.4.3 Do the labels give the ultraviolet lamp model designation? YES___NO___

2.5.5 Provide description of location of all labels covered under Items 2.5.1, 2.5.2 and 2.5.3. The description may include photographs or diagrams of all views of the product with the placement of all labels clearly indicated and with a dimension reference scale. DESCRIPTION ATTACHED? YES___NO___

2.6 User Information

Each manufacturer of a sunlamp product and ultraviolet lamp shall provide or cause to be provided to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, instructions for safe use.

Submit copies of all instructions which you provide to users as required by 21 CFR 1040.20(f). COPIES ATTACHED? YES___NO___

2.6.1 Do the user instructions contain a reproduction (color optional) of the label required by 1040.20(d)(1) and is it prominently displayed at the beginning of the instructions? YES___NO___

2.6.2 Do the instructions state "DANGER-Ultraviolet radiation. Follow instructions. As with natural sunlight, overexposure can cause eye injury and sunburn; repeated exposure may cause premature aging of the skin and skin cancer. Medications or cosmetics applied to the skin may increase your sensitivity to ultraviolet light. Consult physician before using lamp if taking any medication or if you believe yourself especially sensitive to sunlight," as required by 1040.20(f)(1)(ii)? YES___NO___

2.6.3 Do the instructions contain a statement of the maximum number of people who may be exposed to the product at the same time and a warning that only that number of protective eyewear has been provided? YES___ NO___

If yes, maximum number of people who may be exposed at the same time? _____

2.6.4 Do the instructions contain information for obtaining repairs and recommended replacement components and accessories which are compatible with the product, including compatible protective eyewear, ultraviolet lamps, timers, reflectors, and filters, and which will, if installed or used as instructed, result in continued compliance with the standard? YES___ NO____

P A R T 3

ULTRAVIOLET LAMPS

(THIS PART IS TO BE COMPLETED FOR ULTRAVIOLET LAMPS INTENDED FOR USE IN ANY SUNLAMP PRODUCT TO INDUCE SKIN TANNING AS DEFINED IN 21 CFR 1040.20(b)(9) AND WHICH ARE SOLD SEPARATELY FROM SUCH PRODUCTS(s)).

3.1 Attach a description of the lamp including a picture or diagram of it. This picture or diagram may be used to identify the location of labels requested in item 3.6. DESCRIPTION ATTACHED? YES___NO___

3.2 What kind of base is used on the lamp? _____
Types and description of various standard lamp bases can be found in American National Standards (ANSI) publications C81.10, C81.20, C81.30, and C81.40 all published in 1976. If the lamp base is not one of those listed in ANSI (C81.10 through C81.40) 1976 attach a description a a picture or drawing. DESCRIPTION ATTACHED? YES___NO___

3.3 List representative examples of sunlamp products which the lamp is designed to fit.

Manufacturer	Model

LIST ATTACHED? YES___ NO___

3.4 Compliance with Labeling Requirements

3.4.1 Submit a sample of the required certification label, or facsimile if the label is not available at the time of reporting or is inscribed on the reported lamp or lamp packaging. SAMPLE ATTACHED? YES___ NO___

3.4.1.1 Is the certification label affixed to the lamp? YES___ NO___ If no, is the certification label affixed to the packaging? YES___ NO___

3.4.2 Submit a sample of the required identification label, or facsimile if the label is not available at the time of reporting or is inscribed on the reported lamps or lamp packaging. SAMPLE ATTACHED? YES___ NO___

3.4.2.1 Is the identification label affixed to the lamp? YES____ NO____ If no, is the identification label affixed to the packaging? YES____ NO____

3.4.2.2 If the identification label is affixed to the packaging, is the manufacturer's name, complete address, place of manufacture, and the month and year of manufacture affixed or inscribed on the lamp? YES____ NO____

If yes, and expressed in code or symbols, supply the key to the code or symbols.

_____

_____

KEY ATTACHED? YES___NO___

What is the location of the coded information?

_____

PICTURE OR DIAGRAM ATTACHED? YES____ NO____

3.4.2.3 Is the month and year of manufacture provided clearly and legibly without abbreviation on the lamp or lamp packaging and with the year shown as a four-digit number as in the following example?
Manufactured: August 1976. YES____ NO____

3.4.3 Submit a sample of the warning label (or facsimile if not available at the time of reporting or is inscribed on the reported product) required to be affixed to the lamp by 21 CFR 1040.20(d)(2). SAMPLE ATTACHED? YES____ NO____

3.4.3.1 Is the warning label legible and clearly visible when the reported lamp is installed and ready for use?

YES____ NO____ If no, explain_____

_____

_____

3.4.3.2 Is the warning label permanently affixed or inscribed on the reported lamp? YES____ NO____

3.4.3.3 Does the warning label contain the words "SUNLAMP - DANGER - ULTRAVIOLET RADIATION. FOLLOW INSTRUCTIONS"? YES____ NO____

3.4.3.4 Does the warning label contain the words: "Use ONLY in fixture equipped with a timer"? YES___NO____

3.4.3.5 Does the warning label give the ultraviolet lamp model designation? YES____ NO____

3.4.4 Identify the location of each required label. This may be done on the picture or drawing in item 3.1.

LOCATION INDICATED:

CERTIFICATION LABEL_____

IDENTIFICATION LABEL_____

WARNING LABEL_____

3.5 User Information

Each manufacturer of an ultraviolet lamp shall provide or cause to be provided to purchasers and upon request to others at a cost not to exceed the cost of publication and distribution, instructions for safe use, including the following mechanical and safety information as applicable:

3.5.1 Submit copies of all instructions which you provide to users. COPIES ATTACHED? YES___NO___

3.5.2 Do the instructions contain reproductions of the labels as required by 1040.10(f)(2)? YES___NO___

3.5.3 Do the instructions contain a prominently displayed statement with the words "DANGER - Ultraviolet radiation. Follow instructions. As with natural sunlight, overexposure can cause eye injury and sunburn; repeated exposure may cause premature aging of the skin and skin cancer. Medications or cosmetics applied to the skin may increase your sensitivity to ultraviolet light. Consult physician before using lamp if taking any medication or if you believe yourself especially sensitive to sunlight," as required by 1040.20(f)(2)(ii)? YES____NO____

3.5.4 Do the instructions contain the warning that the instructions accompanying the sunlamp product should always be followed to avoid or minimize potential injury? YES____ NO____

P A R T 4

DESCRIPTION OF EMISSION CHARACTERISTICS

(THIS PART SHOULD BE COMPLETED BY ULTRAVIOLET LAMP MANUFACTURERS AND SUNLAMP PRODUCT MANUFACTURERS WHO PURPOSELY MODIFY THE SPECTRAL CHARACTERISTICS OF THE ULTRAVIOLET LAMPS).

Before proceeding to the questions below, consult the guidance given in Appendix B.

4.0 Spectral Characteristics

4.1 Description of procedures for spectroradiometric measurement:

(a) At what distance from the product were the spectral irradiance measurements made? _____ meters.

(b) What spectral irradiance standards were used?

1. Source of standard _____

2. When last calibrated _____

3. Uncertainty _____

(c) At what wavelengths was the spectral irradiance of radiation from the product measured? _____

4.2 Attach a graphical plot of the spectral irradiance from the product in the 180-710 nm wavelength range. Plot should be on a semilog graph with the spectral irradiance on the logarithmic scale. GRAPHICAL PLOT ATTACHED? YES___NO___

4.3 Give the spectrally integrated irradiance values (Watts/cm^2) and uncertainties over the following wavelength ranges and the irradiance ratio calculated from the 180-260 and the 260-320 nm wavelength ranges:

180 - 260 nm _____
(Value) (Uncertainty)

260 - 320 nm _____
(Value) (Uncertainty)

320 - 400 nm _____
(Value) (Uncertainty)

400 - 710 nm _____
(Value) (Uncertainty)

Irradiance Ratio (1040.20(c)(1)) _____
(Value (Uncertainty)

Describe how you estimated the uncertainties in your spectroradiometric measurements. STATEMENT ATTACHED? YES___NO___

4.4 Attach a description of the equipment used for spectral irradiance measurements. Include diagrams of light path, position, make, model and type of various optical equipment and electronics used. DESCRIPTION ATTACHED? YES___NO___

4.4.1 If you manufacture only the sunlamp product, which lamp(s) were used in these tests?
LIST ATTACHED? YES___NO___

4.4.2 If you manufacture only ultraviolet lamps, describe which sunlamp products or fixtures, if any, were used in these tests. DESCRIPTION ATTACHED? YES___NO___

PART 5

QUALITY CONTROL, LIFE AND RELIABILITY TEST INFORMATION RELATED TO PRODUCT RADIATION SAFETY

5.1 Quality Control Tests Made Before Product is Manufactured

5.1.1 What tests are conducted to test the design and engineering of the product? NONE_____ LIST OF TESTS ATTACHED_____

5.1.2 Describe the tests or checks made on incoming components prior to their acceptance to assure that the final product will comply with the Federal performance standard for sunlamp products (21 CFR 1040.20).

NONE _____DESCRIPTION ATTACHED _____

5.2 Quality Control Tests or Checks Made During and After Manufacture of Product. Describe the tests or checks conducted on the product during and after manufacture. Include description of sampling plan used, if any; if tests are conducted on a 100% basis, so state. Also, describe any rejection criteria.

	NO TESTS	DESCRIPTION ATTACHED
(a) Timer	_____	_____
(b) Means to terminate emission	_____	_____
(c) Certification Label	_____	_____
(d) Identification Label	_____	_____
(e) Warning Label	_____	_____
(f) Protective Eyewear	_____	_____
(g) Irradiance Ratio	_____	_____
(h) Others (Specify)	_____	_____
_____		_____
_____		_____

5.3 Action Upon Rejection

5.3.1 What happens to rejected units?

Units destroyed or scrapped? YES___NO___

Units repaired? YES____NO___

If a unit is repaired, is it retested for compliance with the quality control criteria which it initially failed? YES_____NO_____

5.3.2 Are accepted units subject to quality audits? YES___NO___
If so, describe audit plan and the tests or checks which are made. DESCRIPTION ATTACHED? YES____NO____

5.4 Life and Reliability Tests

Attach information for all life and reliabiity tests on the product and its components. If any life tests are done on an accelerated aging basis, so indicate and provide details of the procedures and the formula or factors used in the accelerated tests. Provide this information for the following tests:

	NO TESTS	INFORMATION ATTACHED
(a) Timer	_____	_____
(b) Means to terminate emission	_____	_____
(c) Certification Label	_____	_____
(d) Identification Label	_____	_____
(e) Warning Label	_____	_____
(f) Protective Eyewear	_____	_____
(g) Irradiance Ratio	_____	_____
(h) Mechanical Durability	_____	_____
(i) Others (Specify)	_____	_____
_____	_____	_____
_____	_____	_____

5.5 List the most common malfunction or replacement problems that would affect the radiation safety of the product. Attach detailed information on each. Report number of such malfunctions that have come to your attention.

	MALFUNCTION OR PROBLEM	NO. IN LAST 12 MONTHS	DETAILS ATTACHED
(a)			
(b)			
(c)			
(d)			
(e)			

5.6 Submit copies of all quality control tests and check sheets employed for incoming component checks, manufacturing checks and final acceptance checks. FORMS ATTACHED? YES___NO___

APPENDIX A. TANNING BOOTHS, SAFETY CONCERNS AND EQUIPMENT RECOMMENDATIONS

The rapid development of the tanning booth industry has disclosed numerous safety problems. In order to minimize the hazards involved in the use of these products, FDA makes the following equipment recommendations to manufacturers of tanning booths or other similar equipment for whole body exposure for tanning purposes. These recommendations are in addition to the requirements of the Sunlamp Product Performance Standard 21 CFR 1040.20 (copy enclosed).

1. User Positioning in the Booth - The irradiance to which a user is exposed depends upon the distance the user is from the lamp. The irradiance at contact can be as much as five times higher than that at a distance of 12 inches. Serious burns can occur if the proper exposure distance is not maintained. Installing hand rails, markings on the floor or other suitable physical aids will assist in keeping the user at the proper exposure distance from the sunlamps.

2. Timer Error - The ultraviolet radiation intensity usually found inside a tanning booth is relatively high when compared to the sun or the intensities associated with smaller home portable sunlamps. Because of this, allowable exposure times are shorter. Therefore, more accurate control of exposure duration is necessary to decrease the risk of overexposure, and injury. A timer having a maximum error of $\pm$10% of any selected timer interval is sufficiently accurate.

3. Protective Eyewear - Exposure of a person's eyes to ultraviolet radiation may result in burns, yet persons being exposed need to see well enough to maintain balance and to rapidly locate the door and exit safely should that be necessary. It is important that protective eyewear be provided that protects from ultraviolet radiation and allows adequate vision.

4. Temperature Control - Operation of sunlamps can increase the temperature in an enclosed booth. A large increase in temperature might cause fainting and subsequent injury. Booths which keep the temperature below 100 °F (38 °C) would not be cause for concern.

5. Electrical Safety - If potential electrical hazards in the booth are not controlled, users, operators, and service personnel may be seriously injured. Elevated temperatures cause perspiration that enhances the possiblility and severity of an electric shock. Even without perspiration, the skin may come into contact with the interior surfaces which house lamps and ballasts that carry large amounts of current. There is a potential for electric shock without proper circuit design and insulations.

In addition, there are potential hazards to operators and service personnel. Changing lamps, turning on the device, etc., can be a hazard if the device is not grounded properly and if ground fault protectors are not included. There is also the possibility of a fire due to circuit overloads, short circuitry in the wiring

and the use of flammable material. Electrical hazards will be minimized in booths that conform to currently recognized electrical standards for such equipment.*

6. Mechanical Construction - The collapse of a booth might cause electrical shock, fire or direct physical injury. This can be prevented by designing the booth to have enough strength and rigidity to resist the stress of use and to withstand the impact of a falling person.

7. Protection from Lamps - A person can be cut and seriously injured by falling into or bumping against bare sunlamps. This could be prevented by use of physical barriers around the lamps such as heavy wire grids or ultraviolet transmitting plastics which are sturdy enough to withstand the impact of a falling person.

8. Access and Support - Rapid entrance into and exit from the booth are essential in emergencies. This can be assured by use of doors which open outwardly and are easily opened from both the inside and the outside of the booth. The potential for injuries from falls can be reduced by providing hand rails and floors which have adequate traction for wet or dry bare feet.

*1. American National Standard Institute; Association for the Advancement of Medical Instrumentation; American National Standard Safety Current Limits for Electromedical Apparatus; January 19, 1978, ANSI/AAMI, SCL 12/78. A copy of this standard may be obtained by writing to: AAMI, Suite 602, 1901 N. Fort Myer Drive, Arlington, Va. 22209.

2. International Electrotechnical Commission, Publication 601-1; Safety of Medical Electrical Equipment Part 1: General Requirements, 1977, Bureau Central de la Commission Electrotechnique Internationale, Geneva, Switzerland.

APPENDIX B - SPECTRORADIOMETRIC MEASUREMENT AND TESTING PROCEDURES

There are several ways to determine radiometric values which, when correctly executed, yield the same physical values. The Bureau does NOT insist that any one method be used. We offer the following suggestions only to help in establishing the important parameters. Physically valid alternatives are, of course, acceptable.

Measurements whose results are reported should be performed using generally accepted radiometric principles and techniques. The information should be reported in spectral irradiance values (watts $cm^{-2}nm^{-1}$). For sunlamp products, all measurements should be made on the entire device consisting of the light source, any related housing or attachments manufactured or assembled for sale in the configuration in which they are intended to be used; however, if the product has components such as a stand or some other component which does not in any way alter the optical performance of the device, then these may be removed before the device is measured. If the ultraviolet lamp must be mounted in some other housing in order to facilitate the measurements, this should be done in such a manner that the optical performance of the lamp is unchanged.

It is recommended that spectroradiometric measurements on the product be made as follows:

The spectroradiometric measurements on the sunlamp or sunlamp product should be made at the recommended use distance from the product on an optic axis in the direction of maximum emission from the product. If more than one such direction exists, choose the one which relates most closely to the intended uses and normal mounting configuration of the product. The measurements on the continuum part of the spectrum should be made at intervals of 10 nanometers (nm) in the ultraviolet wavelength region below 320 nm in which the device emits. In addition, the spectral lines in the emission should be measured with a sufficiently narrow spectral bandpass so as to adequately measure the level of radiation being emitted in those lines.

The measurements should be made with instruments calibrated against standards of spectral irradiance. These standards should have been calibrated either by U.S. National Bureau of Standards (NBS) or by another laboratory against standards calibrated by NBS using NBS recommended or generally accepted techniques.

The standards should be used immediately before and after the measurements on the product. Alternatively, if you usually refer to the standard after every reading while scanning the wavelength scale you may use that method. The results should be reported in spectral irradiance values (watts cm^{-2} nm^{-1}).

The Bureau of Radiological Health generally recommends 100 percent testing of products for determination of compliance. For some tests and inspections a sampling plan may be appropriate, i.e., use of a sampling procedure whereby release of noncomplying products is prevented by testing

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